



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

TM02/0104

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APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
09/449,178	11/24/99	075	PARDQ, T	2171 01/04/01
First Named Applicant	CLASSEN, 35 USC 154(b) term ext. = 0 Days.			

TITLE OF INVENTION SYSTEM FOR CREATING AND MANAGING PROPRIETARY PRODUCT DATA

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
2 22499-66044	707-104.000	A26	UTILITY	YES	\$620.00	04/04/01

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
- B. If the status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give application number and batch number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

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Notice of Allowability

Application No.
09/449,178

Applicant(s)

Classen

Examiner

Thuy Pardo

Group Art Unit

2171



All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course.

☒ This communication is responsive to Application filed on November 24, 1999.

☒ The allowed claim(s) is/are 1-75.

☐ The drawings filed on _____ are acceptable.

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE **THREE MONTHS** FROM THE "DATE MAILED" of this Office action. Failure to timely comply will result in ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.

☒ Applicant MUST submit NEW FORMAL DRAWINGS

☐ because the originally filed drawings were declared by applicant to be informal.

☒ including changes required by the Notice of Draftsperson's Patent Drawing Review, PTO-948, attached hereto or to Paper No. _____.

☐ including changes required by the proposed drawing correction filed on _____, which has been approved by the examiner.

☐ including changes required by the attached Examiner's Amendment/Comment.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the reverse side of the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

☐ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any response to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 02

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☐ Interview Summary, PTO-413

☐ Examiner's Amendment/Comment

☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

☒ Examiner's Statement of Reasons for Allowance

1. Applicant's Application November 24, 1999 has been reviewed.

2. The following is an Examiner's Statement of Reasons for Allowance:

Chen et al., in "Vaccine Safety Datalink Project: A new tool for improving Vaccine Safety Monitoring in the United States" creates a large cohort for multiple epidemiologic studies of vaccine safety on more than 500000 children 0 to 6 years of age to exam any particular vaccine and adverse event association within the VSD depends not only on the frequency of the vaccination but also on the sensitivity and specificity of the case definition, the background rate for the event, and the magnitude of the risk. **Leet**, patent no. 6,000,828 teaches a computer operated system in which recommended drug treatments are allowed to evolve in response to changing medical information, side effects encountered, and patterns of disease resistance to recommended treatments. **Brynjestad** patent no. 5,908,383 teaches generating a prescription and related instructions according to a treatment plan recommendation for a patient based on the patient's responses. The prior art of record fails to teach or suggest individually or in combination the feature of **analyzing data from one adverse event database to assist in identifying new adverse events associated with the product and identifying a new use for the product responsive to identification of the new adverse event** as set forth in claims 1, 12, 41, and 53.

Claims 2-11, 13-40, 42-52, and 54-75 being further limiting to claims 1, 12, 41, and 53 are also allowed.

Serial Number: 09/449,178
Art Unit: 2171

Page 3

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thuy Pardo, whose telephone number is (703) 305-1091. The examiner can normally be reached Monday through Thursday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas G. Black, can be reached at (703) 305-9707. The fax phone number for this Group is (703) 308-5403.

Any inquiry of a general nature of relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 305-9600.

4. **Any response to this action should be mailed to:**

Commissioner of Patents and Trademarks

Washington, D.C. 20231

or faxed to:

(703) 308-9051, (for formal communications intended for entry)

Or:

(703) 308-5359, (for informal or draft communications, please label

"PROPOSED" or "DRAFT")

Hand-delivered responses should be brought to Crystal Park II, 2121 Crystal Drive, Arlington, VA., Sixth Floor (Receptionist).



Thuy Pardo
December 28, 2000



WAYNE AMSBURY
PRIMARY PATENT EXAMINER